

**Amendments to the Drawings:**

The replacement sheet of drawings filed herewith includes changes to Figures 3 and 4. This sheet, which include(s) Figures 3 and 4, replaces the original sheet including Figures 3 and 4.

Attachment: One Replacement Sheet

### **REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment is respectfully requested. Upon entry of the foregoing amendment, claims 1-28 and 33 are pending in the application, with 1, 2, 11, 12, 22, 25, and 28 being the independent claims. Claims 1, 11, 24 and 28 have been amended. Claims 29-32 have been canceled without disclaimer of or prejudice to the subject matter contained therein. Claim 33 has been added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

#### **Substance of Examiner Interview of February 1, 2006**

The Applicant appreciates the courtesy extended by the Examiner to Applicant's representative during the interview held on February 1, 2006. The substance of the interview pertained to claim 1 and a discussion of the disclosure of U.S. Patent No. 5,817,101 to Fiedler. A proposed amendment of claim 1 to include that in a post stent deployment position the entire stent retention portion of the sheath remains distal of a fixed seal of the catheter was agreed to distinguish over Fiedler, if a length of the sheath stent retention and stent retraction portions were more precisely defined with respect to a respective length of the catheter stent retention and sheath retraction sections. The Examiner further suggested positively reciting the element of a stent in claim 1 to clarify the meaning of "a compressed stent length" that is currently used throughout the claim.

#### **Objections to Disclosure**

The Examiner objected to the disclosure for the following informalities: reference numerals 64 and 75 mentioned in the specification were absent from the drawings; and claim 24 did not include a period at the end of the claim. Applicant submits herewith a replacement sheet of drawings including Figure 3 with reference number 75 added, and Figure 4 with reference number 64 added. In addition, claim 24 has been amended to include a period. Accordingly these objections have been rendered moot.

Applicant notes the above amendment of the specification that corrects an error identified by Applicant in the description of the present invention. No new matter has been added by this amendment as it merely corrects and clarifies the previously described structure.

35 U.S.C §112 Rejections

Claims 1 and 23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Particularly in claim 1, the Examiner found it unclear whether the stent or sheath stent retention portion extended for a compressed stent length. This rejection of claim 1, as well as claim 23 that depends therefrom, has been rendered moot by the amendment of claim 1 above.

35 U.S.C. §103 Rejections

Claim 1, 11, 23 and 24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fiedler (U.S. Patent 5,817,101) in view of Lukic *et al.* (U.S. Patent 5,709,703) and Mager *et al.* (U.S. Patent 5,326,011). The Examiner states that Figures 1-3 of Fiedler discloses:

catheter 22 having a guidewire lumen 24 and pressurizing lumen 26, fixed seal mount (the portion of catheter 22 which supports seal 38), sheath 36 having a movable seal mount (the portion of sheath 36 which supports seal 40), a stent retention portion of said sheath (the portion of sheath 36 which surrounds stent 50 prior to deployment), a stent retraction portion of said sheath (the proximal portion of sheath 36 which surrounds seal 38 prior to stent deployment), first seal structure 38 and second seal structure 40.

Office Action p. 2-3. The Examiner notes that “Fiedler fails to disclose a ‘stent plunger’ to provide backing for the stent” but notes Lukic teaches “a stent should be supported by a rigid stop 37, 41 apparently in order to prevent it from migrating proximally within the sheath during sheath retraction as well as providing the advantage of preventing the stent from scratching the catheter.” Office Action p. 4. The Examiner states it would have been obvious to modify the catheter of Fiedler to include Lukic’s “rigid stop 37, 41”, separate from Fiedler’s flexible seal 38,

to arrive at Applicant's claimed stent plunger.<sup>i</sup> Presumably the "'rigid stop, *i.e.*, stent plunger," of the modified Fiedler catheter would be distal of flexible seal 38 and secured about a proximal end of stent 50 to prevent the stent from scratching the sheath, as is the only stated purpose of the structure in the Lukic patent.

The Examiner does not state what structure he is relying on in Fiedler, or the other cited references, for the claimed:

"a sheath retraction section" of the catheter that **"extends from said stent plunger for at least a compressed stent length in a second direction which is opposite said first direction to a fixed seal mount fixed to said catheter;"**

"a fluid receiving chamber section" of the catheter that **"extends from said fixed seal mount in said second direction** for at least a compressed stent length to a maximum fluid receiving chamber extension length;"

a sheath "stent retention portion ... extending for at least a compressed stent length;" and

a sheath "stent retraction portion ... extending for at least a compressed stent length from said stent retention portion of said sheath." Instead, the Examiner states that "[a]s to the limitations in claim 1, lines 9-10, 13-14, 26 and 29-31 referring to a compressed stent length, it is noted that the stent itself is not claimed [and Fiedler] is inherently capable of holding a stent which is shorter than the stent shown in the figures and thus meets these limitations in the claim." Office Action pp. 4-5.

Applicant respectfully traverses the Examiner's rejections. In accordance with the Examiner's suggestion, Applicant has amended independent claims 1 and 11 to positively recite a stent and a stent graft, respectively, in order to clarify the limitation in claim 1 of "a compressed stent length" and the limitation in claim 11 of "a compressed stent graft length." Further Applicant has amended claims 1 and 11 to relate the length of the sheath's stent/stent graft retention portion in the sheath's pre deployment position with respect to the catheter's compressed stent/stent graft retention section; and to relate the length of the sheath's stent/stent

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<sup>i</sup> In fact item 37 of Lukic is a "coverage tube means" that is "a tube of thermoformable material *heat shrunk* over the proximal end portion 78 of the stent 7 and the core 5 [with a radiopaque] ring 41 ... embedded in the tube." Lukic col. 7, line 66 – col. 8, line 16. The only stated purpose of this configuration is scratch

graft retraction portion in the sheath's pre deployment position with respect to the catheter's sheath retraction section. Applicant notes that fairly read Fiedler fails to teach the aforementioned limitations, *inter alia*, as Fiedler does not disclose a catheter having a sheath retraction section or a sheath having a stent/stent graft retraction portion so described. However to move this case to allowance, and as previously discussed with the Examiner during the Examiner Interview, each of the claims includes the limitation that in the post stent/stent graft deployment position the entire stent/stent graft retention portion of the sheath remains distal of the fixed seal mount. Fiedler does not disclose, teach or suggest a catheter having a sheath with a stent retention portion that remains entirely distal of a fixed seal after deployment of the stent.

Accordingly, independent claims 1 and 11 are patentable over Fiedler in combination with Lukic and Mager, as neither of the secondary references makes up for the deficiencies of Fiedler. Claims 23 and 24 depend from and add further limitations to claim 1 and are patentable for that reason alone. While it is not necessary to address the Examiner's rejection of the dependent claim at this time, Applicant reserves the right to support their patentability, when necessary.

Claims 28-32 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Randall *et al.* (US Patent 6,514,261). Essentially the Examiner states that Randall discloses or can be modified to disclose every feature of claim 28 to include a "spacer 12 which is loosely contained within the stent containment sheath 10 and outside the sheath retraction section [wherein] [s]pacer 12 is inherently sized to substantially interfere with the kinking of the stent containment sheath" when the sheath is bent. Office Action p. 5. Claims 29-32 have been canceled, accordingly the Examiner's rejections of these claims will not be summarized.

Applicant has amended claim 28 to recite that the anti-kinking spacer is a helical spring having windings with planar opposing surfaces, wherein each winding has a tapered thickness from a larger thickness near a central longitudinal axis of the helix to a smaller thickness at an outer radial edge of the winding such that the windings have frustum-like cross-sections. The amendment is supported by disclosure in the specification found, *inter alia*, on page 10, lines 6-9 with reference to FIG. 8, and does not introduce new matter into the application. Spring 12 of

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protection for the sheath. *Id.* at col. 7, lines 61-66. Accordingly, the Fiedler catheter modified in view of this teaching of Lukic does not render obvious this feature of Applicant's invention.

catheter 11 disclosed in Randall is described as merely a compressed spring and does not teach or suggest such a winding having a tapered thickness from a larger thickness near a central longitudinal axis to a smaller thickness at an outer radial edge and having a frustum-like cross-section. Accordingly independent claim 28 is patentable over the Randall patent.

New claim 33 depends from and adds further limitations to claim 28 and is patentable for that reason alone.

Examiner's Allowance of Claims 2-10, 12-22 and 25-27

Applicant acknowledges the Examiner's allowance of claims 2-10, 12-22 and 25-27. In view of the foregoing, all pending claims in the application should now be in condition for allowance.

**CONCLUSION**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Respectfully submitted,

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